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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422, 423, 438, and 498

[CMS-4185-CN]

RIN 0938-AT59

Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correction.

SUMMARY: This document corrects technical and typographical errors that appeared in the final rule published in the April 16, 2019 **Federal Register** titled "Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021".

DATES: Effective Date: The corrections to the preamble of the final rule published on April 16, 2019 (84 FR 15680), are effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The correction in instruction 8 (§ 423.120) is effective June 17, 2019. The corrections in instructions 5 (§ 422.561), 6 (§ 422.562), 7 (§ 422.633), and 9 (§ 423.120) are effective on January 1, 2020. The correction in instruction 4 (§ 422.107(d)) is

effective January 1, 2021.

FOR FURTHER INFORMATION CONTACT: Theresa Wachter, (410) 786–1157.

Cali Diehl, (410) 786–4053.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2019-06822 of April 16, 2019 (84 FR 15680), there were a number of technical and typographical errors that are identified and corrected in the Correction of Errors section of this correcting document. The provisions in this correction document are effective as if they had been included in the document published April 16, 2019.

II. Summary of Errors

A. Summary of Errors in the Preamble

On page 15680, in our listing of the effective dates, we made an error in a regulatory citation.

On page 15713, in our discussion of dual eligible special needs plans and contracts with states, we made a typographical error.

On page 15736, in our discussion of integrated grievances, we made an error in regulatory citation.

B. Summary of Errors in the Regulations Text

On page 15828, in the regulation text for §422.107(d), we made a typographical error.

On page 15834, in the regulation text for §422.561, we inadvertently misspelled the term “complaint” and in §422.562, we made errors in two cross-references.

On page 15838, in the regulation text §422.633, we made inadvertent technical errors

in language of two regulatory provisions regarding integrated reconsideration.

On page 15840, we made errors in the placement of the regulatory text revisions for §423.120(c)(6)(iv) and (v). We inadvertently included the revisions for §423.120(c)(6)(iv) with the amendments effective June 17, 2019 (instead of January 1, 2020) and the revisions for §423.120(c)(6)(v) with the amendments effective January 1, 2020 (instead of June 17, 2019).

III. Waiver of Proposed Rulemaking

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the Federal Register before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the Federal Register and provide a period of not less than 60 days for public comment. In addition, section 553(d) of the APA, and section 1871(e)(1)(B)(i) of the Act mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the notice and comment and delay in effective date APA requirements; in cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act provide exceptions from the notice and 60-day comment period and delay in effective date requirements of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process are impracticable, unnecessary, or contrary to the public interest. In addition, both section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) of the Act allow the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest

and an agency includes a statement of support.

Section 553(d) of the APA ordinarily requires a 30-day delay in effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued.

We believe that this correcting document does not constitute a rule that would be subject to the notice and comment or delayed effective date requirements of the APA or section 1871 of the Act. This correcting document corrects technical errors in the preamble and regulation text of the final rule but does not make substantive changes to the policies that were adopted in the final rule. As a result, this correcting document is intended to ensure that the information in the final rule accurately reflects the policies adopted in that final rule.

In addition, even if this were a rule to which the notice and comment procedures and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the final rule or delaying the effective date would be contrary to the public interest because it is in the public's interest to ensure that final rule accurately reflects our policies. Furthermore, such procedures would be unnecessary, as we are not altering payment eligibility or benefit methodologies or policies, but rather, simply implementing correctly the policies that we previously proposed, received comment on, and subsequently finalized. This correcting document is intended solely to ensure that the final

rule accurately reflects these policies. Therefore, we believe we have good cause to waive the notice and comment and effective date requirements.

IV. Correction of Errors

In FR Doc. 2019-06822 of April 16, 2019 (84 FR 15680), make the following corrections:

A. Corrections of Errors in the Preamble

1. On page 15680, first column, fourth full paragraph (Dates section), line 9, the reference "423.120(c)(6)(iv)" is corrected to read "423.120(c)(6)(v)".

2. On page 15713, third column, second full paragraph, line 29, the phrase "arrange for" is corrected to read "arranges for".

3. On page 15736, first column, first partial paragraph, line 6, the reference "§422.630(e)(2)(ii)" is corrected to read: "§ 422.630(e)(2)".

B. Corrections of Errors in the Regulations Text

§ 422.107 [Corrected]

4. Effective January 1, 2021, on page 15828, third column, in § 422.107(d), the phrase "or arrange for" is corrected to read "or arranges for".

§ 422.561 [Corrected]

5. Effective on January 1, 2020, on page 15834, first column, in § 422.561, in the definition of "Integrated grievance," the term "compliant" is corrected to read "complaint".

§ 422.562 [Corrected]

6. Effective on January 1, 2020, on page 15834, in § 422.562--

a. In paragraph (b)(2), the reference, "§ 422.631" is corrected to read, "§ 422.631(c)".

b. In paragraph (b)(4)(ii), the reference "§ 422.633(f)" is corrected to read "§ 422.633(e)".

§ 422.633 [Corrected]

7. Effective on January 1, 2020, on page 15838, in § 422.633—

a. In paragraph (f)(1), the phrase, "no longer than" is corrected to read "no later than".

b. In paragraph (f)(2), the phrase "of receipt for" is corrected to read "of receipt of".

§ 423.120 [Corrected]

8. Effective June 17, 2019, on page 15840, in second column, amendatory instruction 28 for § 423.120 and its corresponding text is corrected in its entirety to read as follows:

28. Effective June 17, 2019, § 423.120 is amended by revising paragraph (c)(6)(v) to read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(c) * * *

(6) * * *

(v)(A) CMS sends written notice to the prescriber via letter of his or her inclusion on the preclusion list. The notice must contain the reason for the inclusion on the preclusion list and inform the prescriber of his or her appeal rights. A prescriber may appeal his or her inclusion on the preclusion list under this section in accordance with part 498 of this chapter.

(B) If the prescriber's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:

(1) The notice described in paragraph (c)(6)(v)(A) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the prescriber's appeal rights concerning the revocation.

(2) The appeals of the prescriber's inclusion on the preclusion list and the prescriber's revocation must be filed jointly by the prescriber and, as applicable, considered jointly under part 498 of this chapter.

(C)(1) Except as provided in paragraph (c)(6)(v)(C)(2) of this section, a prescriber will only be included on the preclusion list after the expiration of either of the following:

(i) If the prescriber does not file a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list upon the expiration of the 60-day period in which the prescriber may request a reconsideration.

(ii) If the prescriber files a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list effective on the date on which CMS, if applicable, denies the prescriber's reconsideration.

(2) An OIG excluded prescriber is added to the preclusion list effective on the date of the exclusion.

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§ 423.120 [Corrected]

9. Effective on January 1, 2020, on page 15840, beginning in the second column, amendatory instruction 29 for § 423.120 and its corresponding text is corrected in its entirety to read as follows:

29. Section 423.120 is further amended by—

a. Revising paragraph (c)(6)(iv); and

b. Adding paragraphs (c)(6)(vii) and (viii).

The revision and additions read as follows:

§ 423.120 Access to covered Part D drugs.

* * * *

(c) * *

(6) * *

(iv) With respect to Part D prescribers who have been added to an updated preclusion list but are not currently excluded by the OIG, the Part D plan sponsor must do all of the following:

(A) Subject to all other Part D rules and plan coverage requirements, and no later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received a Part D drug prescribed by an individual added to the preclusion list in this update and whom the plan sponsor has identified during the applicable 30-day period.

(B)(1) Subject to paragraph (c)(6)(iv)(B)(2) of this section, must ensure that reasonable efforts are made to notify the individual described in paragraph (c)(6)(iv) of this section of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(A) of this section.

(2) Paragraph (c)(6)(iv)(B)(1) of this section applies only upon a prescriber writing a prescription in Medicare Part D when:

(i) The plan sponsor has enough information on file to either copy the prescriber on the notification previously sent to the beneficiary or send a new notice informing the prescriber that they may not see plan beneficiaries due to their preclusion status; and

(ii) The claim is received after the claim denial or reject date in the preclusion file.

(C) Must not reject a pharmacy claim or deny a beneficiary request for reimbursement for a Part D drug prescribed by the prescriber, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (c)(6)(iv)(A) of this section.

* * * * *

(vii)(A) Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the prescriber's reenrollment bar.

(B) Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the prescriber had the prescriber been enrolled and then revoked.

(C) Except as provided in paragraph (c)(6)(vii)(D) of this section, an individual, regardless of whether the individual is or was enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted. Factors that CMS considers in making such a determination are

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- (1) The severity of the offense;
- (2) When the offense occurred; and
- (3) Any other information that CMS deems relevant to its determination.

(D) In cases where an individual is excluded by the OIG, the individual must remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

(viii) Payment denials under paragraph (c)(6) of this section that are based upon the prescriber's inclusion on the preclusion list are not appealable by beneficiaries.

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Dated: June 3, 2019.

Ann C. Agnew,

Executive Secretary to the Department,

Department of Health and Human

Services.

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